DEPARTMENT OF HEALTH AND HUMAN SERVICES

DMB

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Food and Drug Administration

[Docket No. 00N–1599]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Use of Impact-Resistant Lenses in Eyeglasses and Sunglasses

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Use of Impact-Resistant Lenses in Eyeglasses and Sunglasses (OMB Control Number 0910–0182)—Extension

Under section 519 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(i)), every manufacturer or importer of a device intended for human use shall establish and maintain records. This regulation is designed to protect the eyeglass and sunglass wearer from potential eye injury resulting from shattering of ordinary eyeglass lenses, and it requires that eyeglasses and sunglasses be fitted with impact-resistant lenses. The regulation in § 801.410(f) (21 CFR 801.410(f)) requires that the results of impact tests and description of the test method and apparatus also be kept for a period of 3 years. These records are valuable to FDA when investigating eye injury complaints.

The expected respondents to this collection are manufacturers of impact-resistant lenses.

In the **Federal Register** of November 28, 2000 (65 FR 70916), the agency requested comments on the proposed collection of information. One comment was received. The comment stated the estimate seems to include only the time for testing, but omitted the cost of the materials and their disposal. It stated that the estimate did not explicitly address whether this testing is destructive in nature. These costs are material.

FDA's attempt at addressing these issues was limited by the Vision Council of America's (VCA) reluctance to provide any more information than what had been included in FDA's original submission. VCA informed FDA that there was a restriction on information because VCA had promised their clients that they would not release certain data that was considered critical. Because of this limited amount of information from FDA's most reliable source (VCA), FDA was limited to the estimated burden that was included in the original submission (OMB control number 0910–0182).

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
80 :.410(f)	30	769,000	23,070,000	.0008	19,225

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]Due to an inadvertent error, the recordkeeping burden hours for § 801.410(f) that appeared in a notice issued in the FEDERAL REGISTER of November 28, 2000, were incorrect. Table 1 of this document contains the correct estimates.

VCA provided sales figures (www.visionsite.org) that were used in estimating the burden for this collection. Beginning in 1998, a growth rate of 2.6 percent for the distribution of lenses began, and it was assumed that this growth rate continued in 1999 and 2000. This resulted in an increase in the number of eyeglasses shipped annually to 89 million lenses shipped by year 2000.

By also assuming that the glass/plastic lenses-produced ratio remained as in previous years (22 percent glass and 78 percent plastic), that glass lenses must be tested individually, and only 5 percent of the plastic lenses must be tested, then 23,070,000 lenses should be tested. This figure was derived by taking 22 percent of 89 million glass lenses (19,600,000) and adding it to 5 percent of the remaining plastic lenses (5 percent x 69,400,000 = 3,470,000).

Next, divide the total tests (23,070,000) by 30 manufacturers to return the annual frequency of recordkeeping figure of 769,000. Previously, FDA and industry experts estimated that on average, each test could be completed and recorded in 3 seconds. Industry, therefore, could complete 1,200 tests per hour. Therefore, it is estimated that the total burden for this collection is 19,225 hours, which is calculated by taking the total records figure (23,070,000) and dividing it by tests per hour (1,200). The total hours was calculated by multiplying the total number of records (23,070,000) and the hours per record (.0008).

There is no burden estimated for maintaining sale or distribution records under § 801.410(e) because firms are retaining their records as a normal and customary business practice for reasons of product liability.

Dated: 3/1/01
March 1, 2001

William Hubbard

William K. Hubbard
Senior Associate
Commissioner for Policy,
Planning, and Legislation
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Sylvette N. Reese